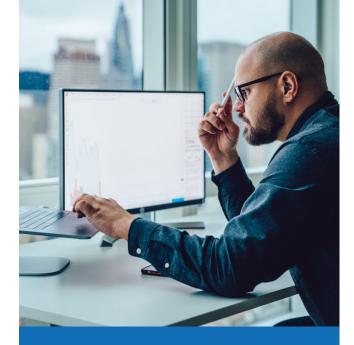CASE STUDY

PHILIPS
◇ *Spectranetics*

Medical Device Leader Streamlines Complaint Handling and Regulatory Reporting to Successfully Navigate Organizational Growth

AssurX

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Jason Hearn
Senior Complaints Manager

OVERVIEW

Spectranetics, part of the Philips Image-Guided Therapy Devices business unit, knew they needed a better way to manage their paper-based complaints process. With AssurX, the company has been able to improve the efficiency and quality of reporting, while creating a more cohesive process during a period of growth.

THE COMPANY

Spectranetics manufactures a wide range of innovative medical devices aimed at helping patients with cardiac and vascular disease live fuller lives. Their products include catheters used for treating coronary and peripheral artery disease, as well as for removing defibrillator leads for implanted pacemakers and cardioverters.

The company also recently received pre-market authorization from the U.S. FDA for its drug-coated balloons, a next-generation treatment used in patients with peripheral artery disease.

MANUAL COMPLAINT REPORTING PROCESS CREATES SIGNIFICANT GAPS

Before deploying Assurx for Complaint Handling, the Spectranetics team used a paper-based complaints process maintained in a legacy IBM database. This involved uploading paper-based complaints to the database, requiring significant manual effort while reducing visibility and control.

The company is subject to numerous regulations globally, including:
- U.S. FDA regulations
- EU MDD and MDR regulations
- Japan's PMDA regulations
- South Korean and Malaysian regulations

In these countries, device manufacturers are required to report adverse events no matter where they occurred, even if they didn't happen in that specific country.

According to Jason Hearn, Senior Complaints Manager overseeing all of Philips IGTD complaints, these regulations drastically increase the work required around reporting complaints.

"One adverse event can result in up to five reports, depending on each country's requirements to sell devices there," says Hearn.

This reporting complexity made it difficult to manage complaints in a timely manner, since the process involved getting signatures on multiple paper forms and manually transcribing the data.

"When we were relying on manual processes, the old system just wasn't sufficient," Hearn says. "There was too much going on to rely on humans as the glue keeping the process together."

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"We needed a system that allowed us to make changes on the fly in terms of adding and removing people to complaint workflows, and that's something we've been able to do with AssurX."

Jason Hearn
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FINDING A FLEXIBLE, CUSTOMIZED SOLUTION

In 2014, Spectranetics decided to implement AssurX Complaint Handling due to its flexibility and customization options. AssurX's streamlined reporting also made it easier to comply with the multitude of global regulatory requirements the company is subject to.

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Spectranetics worked with AssurX to deploy a customized solution that aligned with company workflows and goals. To simplify the regulatory reporting process, Spectranetics created a series of decision trees using yes or no questions that automatically determine reportability under various regulatory frameworks.

PHILIPS ACQUISITION RAISES NEW CHALLENGES

In 2017, Spectranetics was acquired by Philips, which represented a big step forward for the Philips IGTD business unit, but also created new challenges. While Spectranetics initially had a low volume of complaints, the acquisition by Philips and the addition of other business units meant complaint volumes went up overall.

After the acquisition, there was a question as to whether the company would continue using the AssurX system, or whether Philips would choose to implement a different solution. Ultimately, however, they decided to stick with AssurX Complaint Handling because of its robust performance in streamlining the process.

"We've proven that our system is much more efficient than any other solution Philips has," says Hearn.

Another advantage of keeping everything in the AssurX system, Hearn says, was the pricing structure. Concurrent licenses mean that instead of having to buy a license for every single user, the company instead has a set limit.

"We have teams all over the globe working in AssurX," Hearn says. "That means we can work with 80 licenses instead of 160 because half of the team is working when the other half isn't."

Throughout the acquisition process, Spectranetics worked closely with AssurX to customize the Complaint Handling solution to ensure it would work efficiently with the new business units coming in.

"It's heavily customized, and very different from the out-of-box solution," says Hearn. Internal Spectranetics experts would start with an idea on how to customize the software, and then work with the AssurX team to fine-tune it to achieve the company's goals.

"Having everything in one database so we can easily pull the information together is a big win."

Jason Hearn
Senior Complaints Manager

SPECTRANETICS SEES IMPROVED REPORTING DETAIL AND EFFICIENCY

According to Hearn, some of the biggest improvements the company has seen are in terms of data centralization, risk mitigation, and reporting.

Where their previous process involved filling out paper forms and tracking down people for signatures, today all complaint data is accessible from one centralized location.

"Having everything in one database so we can easily pull the information together is a big win," he says. Hearn notes that complaint records now capture far more detail than before, and his team strengthened the process even by adding risk analysis to complaints.

Today, Spectranetics uses decision trees in AssurX to automatically determine reportability in countries where they market their products, including the U.S., Europe, Australia, Brazil, Malaysia, South Korea, Japan, and China.

"We answer the questions, the system determines if it's reportable or not, and then we file the reports according to our process," says Hearn. He adds that his team is even able to submit reports to the U.S. FDA directly from AssurX with one-click submission.

"It's a vast improvement over the previous process," he says. "Even if we wait until day 29, we can still get the report in on time."

IMPROVING CONTROL OVER THE COMPLAINTS PROCESS

As the volume of complaints went up, Hearn notes that the company initially faced a growing backlog of aging complaints. Centralizing complaints in AssurX, however, has helped bring the process into a tighter state of control.

"Because of the flexibility we had within the system, we were able to make changes to the process and get it to the point where we had a more stable, consistent workload."

Hearn says that the level of support AssurX provides has helped lay the foundation for success during a period of change at the company.

"AssurX has always been quick to support us when we have issues or questions," Hearn says. He notes that the company is currently onboarding a new administrator, and that AssurX training has helped him gain confidence and grow in his new role.

FUTURE PLANS WITH ASSURX

Hearn's team is currently working on a second phase of the process that involves updating decision trees and validation documents to deploy an updated version of the system. In the future, manufacturing is looking at using AssurX for non-conformance reporting and linking it with the complaints database.

As for what he learned throughout the process, Hearn says he would tell other manufacturers to set up the database for easy updating with minimal impact on validation.

"My plan moving forward is to set up the system so that we can add product or make changes without having to do much additional validation," he says. "The idea is that we can do low-level changes where we only have to validate the field, without having to validate the information in that field.

From a high-level perspective, Hearn notes that AssurX laid the foundation for a more cohesive team during and after the Philips acquisition.

"People were already somewhat familiar with the software, so getting the data and interpreting it was easier for other business departments to understand," Hearn says. "It really showed that we were one team, and that we were meeting the objective."

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